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10/759,160	01/20/2004	Silke Kohlhase	P24855	6657
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GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			JEAN-LOUIS, SAMIRA JM	
ART UNIT		PAPER NUMBER		
1617				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/759,160	Applicant(s) KOHLHASE ET AL.
	Examiner SAMIRA JEAN-LOUIS	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 February 2008.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 78-136 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 78-136 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/02505) _____
Paper No(s)/Mail Date Sheets (4)

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 02/01/08. Claims 78-136 are currently pending in the application, with claims 19-77 having been cancelled. Accordingly, claims 78-136 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Terminal Disclaimer

The terminal disclaimer filed on 02/01/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. patent application 10/759254 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's argument with respect to the instant claims reciting a cosmetic or dermatological composition that is pearlescent and that Riedel in view Chapin does not teach pearlescent compositions has been considered but is not found persuasive. The claims as previously presented did not recite the limitation of pearlescent and as such

applicant's remarks are moot. Moreover, it should be noted that the recitation of intended use does not further limit a claim drawn to a composition.

Applicant's contention that Riedel mentions polymers as one of many examples of optional ingredients, auxiliaries and additives without reciting specific classes of amphiphilic polymers, associative polymers and/or siloxane polymers is acknowledged but is not found persuasive. Riedel explicitly teaches the addition of polymers as emulsifiers involving both amphiphilic polymers (i.e. polyglycerol 3-dihydroxystearate, also known in the art as Cremophor) and associative polymers such as acrylate/C10-30 alkyl acrylate cross polymer (see Riedel, col. 8, lines 58-59 and 64). Because Riedel teaches the inclusion of polymers in his composition, one of ordinary skill in the art would be motivated to include the aforementioned polymers as emulsifiers as disclosed by Riedel.

Applicant's argument with respect to the fact that the amphiphilic polymers, associative polymers and/or siloxane elastomers disclosed by applicant are not conventionally or routinely added to cosmetic and dermatological compositions has been considered but is not found persuasive. Applicant further contends that Examiner did not cite one single document which discloses the incorporation of an amphiphilic polymer, associative polymer or siloxane elastomer. These arguments again are not found persuasive since Riedel teaches the addition of polymer emulsifiers of both amphiphilic and associative in nature (see col. 8, lines 35-65 and col. 9, lines 3-38).

Moreover, whether or not the aforementioned polymers are all employed in the composition, Riedel clearly recites the inclusion of different types of polymers that can be included in his composition and this necessarily reads on applicant's claims reciting the use of at least one amphiphilic polymer, associative polymer and siloxane elastomer.

Applicant's argument with respect to claims 119-120 reciting a composition that is substantially free of mono- and di-fatty acid esters of glycerol and glycol has been considered but is not found persuasive. The claims as previously presented did not contain claims 119-120 and as such applicant's remarks are moot. Moreover, Examiner respectfully pointed out in the previous Office Action that the term substantially free is a broad term and given that applicant did not provide any clear definition or critical limitation, Examiner interpreted Riedel's incorporation of .2%-10% as being substantially free of the aforementioned fatty acids. Webster's Ninth New Collegiate Dictionary defines the term "substantially" as largely but not wholly that which is specified. In other words, substantially free does not mean absolutely free, therefore Riedel's inclusion of at least .2% of mono- and di-fatty acid esters of glycerol and glycol is substantially free in this instance.

For these reasons, the rejection of claims 19-77 under 103 (a) remains proper and is maintained. In view of applicant's amendment, the following modified 103 (a) Final rejection is being made.

Claim Rejections - 35 USC § 103

It is respectfully pointed out that the recitation "pearlescent" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robbie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 78-136 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Riedel et al. (U.S. 6,558,680 B1) in view of Charlton et al. (U.S. 6,486,106 B1).

Riedel et al. teaches cosmetic or dermatological compositions containing fatty acids, fatty alcohols, non-polar lipids and ethoxylated fatty acid esters (see abstract). In addition, Riedel teaches that such composition can comprise auxiliaries and/or additives such as surfactants (i.e. laureth-4, instant claims 78, 85, 102, 108, 125, and 134; see

column 9, line 15, and lines 17- 38; column 11, lines 14-24), and other usual constituents of cosmetic or dermatological formulations, such as polymers (see column 11, lines 14-24). Riedel also teaches that such a composition can also comprise emulsifiers such as acrylate/C10_30-alkyl acrylate cross polymer which is conventionally known in the art as an associative polymer (see column 8, lines 58-59, which meets the limitations of instant claims 78-79, 98-99, 120, and 130-131), cetyl dimethicone (i.e. trade name Abil Wax 9840) conventionally known in the art as a siloxane elastomer (see table 1, which meets the limitations of instant claims 78-79, 120, and 132-133), PEG-40 hydrogenated castor oil conventionally known in the art as a solubilizer (see column 9, line 5, which meets the limitations of instant claims 115-116), mixtures of emulsifiers containing PEG 30 stearate, or PEG 40 stearate or PEG 100 stearate (instant claims 84, 102, 124, and 134; see col. 9, lines 13 and 18) and ethanol (see column 6, line 65) and further teaches that the composition can be formulated as a skin protection cream, cleansing milk, sunscreen lotion or as a decorative cosmetic (see column 10, lines 1-7, which meets the limitation of claims 78-79 and 120). Moreover, Riedel teaches the use of both amphiphilic polymers (i.e. polyglycerol 3-dihydroxystearate, also known in the art as Cremophor) and associative polymers such as acrylate/C10-30 alkyl acrylate cross polymer in his compositions (see col. 8, lines37-65). Importantly, the composition of Riedel et al. specifically discloses the fatty acids stearic and palmitic (instant claims 80, 86, 102-103, 121, 126, and 134-135) as a preferred embodiment of the invention including the use of the fatty alcohol

cetearyl alcohol and the silicone oil cyclomethicone (instant claims 78-79, 81, 87, 102-103, 110, 113, 120, 122, and 134-135; see example 8).

Riedel et al. does not teach the specific amphiphilic polymer, acrylate/vinyl isodecanoate crosspolymer, recited in claims 82, 88, 102-103, 123, 128, and 134-135). Similarly, Riedel et al. does not specifically teach a skin care composition entailing the addition of component (IV) of at least one of sodium hydroxide and potassium hydroxide.

Charlton et al. teaches a skin wash composition (i.e. dermatological composition) containing 0.1-0.5% stabilizing agents such as the amphiphilic polymer Stabylen 30 (or acrylate/vinyl isodecanoate crosspolymer; instant claims 82, 88, 102-103, 123, 128, and 134-135; see col. 4, lines). Charlton et al. further teaches the addition of 2-5% PEG 150 distearate or PEG 55 propylene glycol oleate as thickeners (see col. 4, lines 41-49) in the skin wash composition. Charlton et al., also teaches the use of neutralizing agents such as sodium hydroxide to neutralize the composition and control the pH of the composition (see column 3, lines 1-12, which meets the limitations of instant claims 78-79, 83, 89, 102-105, 120, and 134-136).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to add sodium hydroxide in order to neutralize the instant cosmetic and dermatological composition of Riedel in view of the fact that such composition may necessitate pH control as disclosed by Charlton et al. Given that Riedel teaches a

cosmetic and dermatological composition of fatty acids, fatty alcohol, ethoxylated esters, surfactant (such as laureth-2), and non-polar lipids, and Charlton et al. discloses that sodium hydroxide can be used as a neutralizing agent, one of ordinary skill would have been motivated to add the sodium hydroxide of Chapin to the composition of Riedel with the expectation of adjusting the pH level of the composition in the absence of evidence to the contrary. Thus, claims 78-79, 83, 89, 102-105, 120, and 134-136 are *prima facie* obvious over the teachings of Riedel in view of Chapin.

Similarly, it would have been obvious to one of ordinary skill to incorporate Stabylen 30 and PEG 150 distearate or PEG 55 propylene glycol oleate since Charlton et al. teaches the inclusion of both Stabylen 30 as a stabilizer (i.e. amphiphilic polymer) along with PEG 55 propylene glycol oleate (or PEG 150 distearate) as stabilizers in his dermatological composition. Given that Riedel teaches a cosmetic and dermatological composition of fatty acids, fatty alcohol, ethoxylated esters, surfactant (such as laureth-2), and non-polar lipids, and Charlton et al. teaches the inclusion of both amphiphilic polymers and associative polymers in dermatological compositions, and given that Chapin discloses that sodium hydroxide can be used as a neutralizing agent, one of ordinary skill would have been motivated to incorporate the amphiphilic and associative polymers for stabilizing and thickening purposes as disclosed by Charlton et al. and neutralize the composition of Riedel et al. with sodium hydroxide with the reasonable expectation of providing a stable dermatological composition.

Regarding the term "substantially free" recited in claim 120, it is considered as a broad term. In view of the lack of guidance in the specification and given that applicant did not point out the critical limitation encompassed by the term, Examiner is interpreting the term to mean that a range of 0.2-10% mono- and di-fatty acid esters of glycerol and glycol in a composition necessarily suggest that such composition is substantially free of such fatty acid esters.

Moreover, while the exact percentage of the ingredients are not disclosed by Riedel, it is generally noted that differences in concentration, ranges or percentages do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454,456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or percentages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of percentage or ranges is the optimum combination of percentages.

Regarding the saponification of the fatty acids as recited in claims 106-107, it is considered that one of ordinary skill in the art at the time of the invention was made would find it obvious to conclude that the composition of Riedel would possess the

same percentage of saponified fatty acids as that disclosed by the applicant given that these compositions both entail the same ingredients, therefore, it would be expected that these ingredients would not lead to no more than 9% of saponified fatty acid acids.

It is further noted that In re Best, 195 USPQ 430, and In re Fitzgerald, 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617